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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,003	01/26/2004	Abraham H. Kryger	20308.CON2	6759
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THORPE NORTH & WESTERN, LLP. 8180 SOUTH 700 EAST, SUITE 200 SANDY, UT 84070				
			EXAMINER BADIO, BARBARA P	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/765,003	<b>Applicant(s)</b> KRYGER, ABRAHAM H.	
	<b>Examiner</b> Barbara P. Badio, Ph.D.	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **First Office Action on the Merits**

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,743,448.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass the treatment of diseases/conditions that are responsive to testosterone therapy. Unlike the cited patent, the instant claims are limited to compositions comprising modified poloxamer lecithin organogel, an arginine ingredient, a tocopherol ingredient and testosterone. However, like the instant invention, the cited patent encompasses the utilization of compositions comprising

Art Unit: 1617

modified poloxamer lecithin organogel, an arginine ingredient, a tocopherol ingredient and testosterone (see claims 1-22 of the cited patent).

The difference in the preamble is noted. However, the skilled artisan would have the reasonable expectation that treatment of diseases as recited by the instant claims would result in minimizing aromatic conversion of testosterone as recited by the cited patent because the claims encompass the utilizing of similar compositions.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the

art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

The instant claims are drawn to a method of treating diseases that are responsive to testosterone therapy utilizing the claimed composition. The diseases encompassed by the instant claims include known and unknown diseases/conditions having vastly different etiology, for the example, the claims encompass the treatment of diabetes, which is due to increase sugar levels and treatment of retinopathy, which is a degenerative disease of the retina. The present specification discloses increase in testosterone levels utilizing the claimed composition. It also discloses that a wide variety of disease or conditions **may be** responsive to testosterone therapy. However, the present specification lacks working examples and/or guidance of the utilizing the claimed composition in the treatment of any disease or condition. Therefore, it lacks correlation between said increase testosterone levels and treatment of a representative number of diseases/conditions. Based on the knowledge in the art at the time of the present invention, the skilled artisan would not expect the claimed composition to be useful in the treatment of the scope of diseases and/or conditions as encompassed by the instant claims. Thus, in order to practice the claimed invention commensurate in scope with the instant claims, the skilled artisan would first have to determine the relationship of low testosterone level and the occurrence of every disease/condition encompassed by the claimed invention before testing the effectiveness of the claimed

Art Unit: 1617

composition in the treatment of each disease/condition as encompassed by the instant claims. The amount of experimentation necessary to make said determination is undue because of the lack of guidance and/or working examples in the present specification.

5. Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Briefly, the claims are drawn to treating diseases/condition that are responsive to testosterone therapy utilizing the claimed topical formulation.

The present specification discloses in Experimental Examples 3 and 4 an increase in testosterone levels utilizing the claimed testosterone composition. However, there is a lack of correlation between said increase testosterone and treatment of a representative number of diseases/conditions and, thus, the present specification lacks adequate description of the presently claimed invention. Adequate written description requires more than a mere indication that "a wide variety of diseases or conditions **may be responsive**" to testosterone therapy or that numerous diseases "can be partially or wholly treated" to testosterone therapy (see for example page 6, last paragraph or page 23, paragraph 3). Some correlation between increase testosterone and treatment of a representative number of diseases is required.

Art Unit: 1617

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 5, 7 and 10-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite for the following reasons:

(a) Claim 1 recites the administration of the claimed composition for the treatment of a disease or a condition. The claim lacks recitation of said disease or condition and, thus, it is unclear what is being treated by the administration of the claimed testosterone therapy.

(b) Claim 5 recites treatment of "chronic kidney disease" and claim 11 recites treatment of "heart disease" without recitation of said chronic kidney disease or heart disease. The art does not teach the treatment of all chronic kidney or heart disease utilizing a single compound and, thus, the skilled artisan in the medical art would not expect the claimed composition to be useful in treatment of all diseases encompassed by claimed invention.

(c) Claim 7 recites treatment of "post anabolic steroid abuse". Testosterone is an anabolic steroid and, thus, it is unclear how applicant is treating said condition utilizing said abused substance, i.e., testosterone.

(d) Claim 10 recites treatment of a disease or condition that is "a predisposition toward prostate cancer". It is unclear what diseases or conditions are

Art Unit: 1617

encompassed by the above-mentioned phrase and, thus, the metes and bound of the claimed invention is indefinite.

- (e) Claims 12-16 recite the treatment of a disease or condition that "results" in "infrequent early morning erections (claim 12), small penis size in prepubertal boys (claim 13), subphysiologic levels of insulin-like growth factor (claim 14), poor muscle strength, cognitive function, mood and energy (claim 15) and anabolic steroid abuse (claim 16). However, it is unclear which diseases and/or conditions would result in the above-mentioned conditions and, thus, the metes and bound of the claimed invention is indefinite.

#### ***Other Matters***

8. It is requested that applicant update the cross-reference section by indicating the patent No. of the parent application.

#### ***Telephone Inquiry***

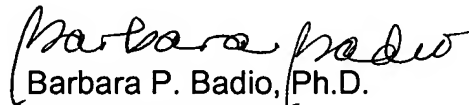
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB

November 14, 2005